NAFTA TECHNICAL WORKING GROUP ON PESTICIDES EXECUTIVE BOARD MEETING

Mexico City, Mexico June 19-20, 2006

SUMMARY REPORT

Introduction

The Executive Board of the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG) on Pesticides met in Mexico City, Mexico, from June 19-20, 2006. The meeting was attended by government officials from Mexico, the United States, and Canada, including Amada Velez (who chaired the meeting), General Director of Food Safety, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SENASICA/SAGARPA), Dr. Karen Dodds, Executive Director of Health Canada's Pest Management Regulatory Agency (PMRA), and Anne Lindsay, Deputy Director of the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP).

Opening Remarks/Country Updates

Amada Velez, the Mexican co-chair, welcomed the Canadian and U.S. delegations, followed by introduction of participants. She reminded everyone that this year is an election year for Mexico and there may be a new government in December 2006. Mrs. Velez outlined two changes in regulations with respect to pesticides in Mexico – a new regulation to register pesticides including generics that includes new guidelines for studying ecotoxicological effect, and regulations related to the disposal of "universal" waste, which includes empty pesticide containers.

Dr. Karen Dodds reported on the current status of the new *Pest Control Products Act*, in force as of June 28, 2006. Dr. Dodds described *Bill C-28*, an Act to amend Canada's *Food and Drugs Act*, which received Royal Assent in November 2005, and how it will make the Canadian Maximum Residue Limit (MRL)-setting process more efficient. She also provided an update on the Canadian proposed policy to revoke the 0.1 ppm General MRL. The extensive comments that were received during the consultation on the proposal have been analyzed, and Canada will release a second consultation document in the near future.

¹ National Service for Sanitary Food Safety and Quality

² Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food

Anne Lindsay reported on various domestic issues, including the current status of EPA's Tolerance Reassessment Program. EPA expects to issue a final rule this summer regarding establishment of the new Registration Review program. This summer, EPA expects to promulgate final regulations outlining new standards for pesticide containers and bulk containment structures. In the future, EPA also plans to issue proposed rules related to pesticide container recycling.

The Secretariat provided a brief update on stakeholder communications. A conference call with stakeholders was held to report out on the December 2005 meeting. Another conference call will be held in July 2006 to report on the outcomes from this Executive Board meeting and to seek stakeholder input to the December 2006 meeting agenda. The Secretariat also outlined the key issues raised by the NAFTA Industry Working Group (IWG) in its official communication to the Executive Board.

Maximum Residue Limits (MRLs/Tolerances)/Technology Gap

A group of representatives from OPP, PMRA, IR-4³ and AAFC⁴ reported on their May 2006 brainstorming session, held to explore innovative solutions for addressing the gap that exists between the U.S. and Canada on pesticide registrations and differences in MRLs or tolerances. The group proposed various measures (retrospective, prospective, technical and policy) for addressing this gap. Retrospectively, the Executive Board recognized the advantages of moving from a commodity-based to chemical-based approach. Prospectively, the Executive Board noted the advantages of moving registrants and regulators to a North American planning approach. The Executive Board endorsed the group's recommendations, including: determining next steps for current commodity-based pilot projects (pulse, tomato, potato); identifying three additional test cases; coordinating registration planning among NAFTA governments, registrants/manufacturers and growers; and, developing a marketing and communications strategy for both the retrospective and prospective approaches. The Executive Board encouraged leads to continue working on these activities as a means of accelerating the closure of the MRL/technology gap.

After Mexico concludes its internal consultations, a trilateral call will be held among the NAFTA countries to identify priority areas for broadening TWG collaboration to address the Mexican MRL/technology gap.

Crop Groupings

As part of long-term technical efforts to address the MRL/technology gap, the Executive Board reviewed and approved the project sheet for the development and implementation of crop groupings. The goal of this effort is to foster harmonization of crop groupings and commodity terminology which will help remove trade irritants due to differences in commodity tolerance levels or MRLs for minor and specialty crops. The Executive Board encouraged IR-4 to share crop grouping proposals submitted to EPA with PMRA and SAGARPA.

2

³ The U.S. Interregional Research Project Number 4 (IR-4 Project)

⁴ The Pest Management Centre of Agriculture and Agri-Food Canada

Good Agricultural Practices (GAP)

Recognizing that the resolution of policy issues associated with GAP is critical to the implementation of approaches identified by the governmental task group for resolving the MRL/technology gap, the Executive Board asked Canada to consider the specific trade irritants identified through the commodity pilots (i.e. pulse, tomato, potato) and determine status and next steps through discussions with the U.S. leads. Canada is currently developing a policy paper on GAP and will share it with the NAFTA partners once completed.

Retrospective Residue Study

U.S. leads undertaking a retrospective analysis of residue studies will report on their progress at the next TWG stakeholder meeting in December. At that time, the Executive Board will consider whether a formal NAFTA TWG project will be pursued in this area.

Residue Trial Efficiencies

The Executive Board encouraged the project leads to continue long-term efforts aimed at residue trial efficiencies, while also focusing specifically on creating incentives for joint reviews. The project leads will clarify the goals and objectives of the project, including how agricultural production figures will be used. The Executive Board charged the project leads to develop a guidance document that outlines basic principles and approaches for establishing the number and location of residue trials for use by registrants and present it for approval at the next TWG meeting.

Zone Map Cluster

The Executive Board approved a communication piece for public release on the zone map cluster. This piece provides an explanation of the interchangeability between zones to facilitate collection and analysis of field trial residue data from Zones 5, 5A, and Zones 1 and 1A to support minor use label expansion (see Appendix A).

MRL Statistical Methodology

The Executive Board noted the successful development and implementation of a harmonized approach to setting MRLs or tolerances through a statistically-based methodology. There was also strong support for the integration of this methodology into the Codex process.

NAFTA Labels

The Executive Board discussed progress with respect to NAFTA Labels and endorsed the NAFTA Label Task Force's next steps which include a progress report at the next TWG stakeholder meeting, including policy, legal and enforcement issues and potential strategies to resolve them, as well as, lessons learned. The Executive Board was pleased in particular, that

certain registrants have already identified potential products for development of a NAFTA label and are exploring formatting issues associated with NAFTA label.

Encouraging Joint Reviews

Canada presented current approaches to NAFTA joint reviews and outlined potential new strategies, such as stakeholder outreach efforts, to encourage joint review submissions. The Executive Board was pleased with the presentation and asked the Joint Review Subcommittee co-chairs to develop a communication piece based on the presentation, for active communication with registrants on joint reviews.

Globally Harmonized System of Classification and Labelling (GHS)

Given that the GHS initiative has the potential to resolve a number of NAFTA label issues, Canada and the U.S. each provided a progress report on GHS implementation, and NAFTA partners will continue to collaborate and exchange information.

Canada's Own Use Import

PMRA presented on Canada's experience with the Own Use Import program and outlined a number of issues being addressed. A Canadian Task Force representing a wide cross-section of stakeholders, including growers, the pesticide industry, health and environmental organizations and officials from federal and provincial governments, was created to initially identify the issues and work through them one by one. The Own Use Import Task Force is expected to finalize its report for public release shortly. The Executive Board asked PMRA to discuss the report's implications with the NAFTA countries to ensure appropriate coordination.

Enforcement and Compliance

The NAFTA partners agreed to establish a network of government officials to exchange information and collaborate on enforcement and compliance issues, including the use of illegal sources of active ingredients to manufacture pesticides.

Inerts/Formulants

Noting the good progress made, the Executive Board encouraged continued interaction among the TWG leads with respect to the reassessment of tolerances for inert/formulant ingredients.

Worker Safety

Mexico presented a project sheet on worker safety with a focus on training and risk communication. The Executive Board noted the advantages of sharing information and results regarding efforts to improve training and understanding by agricultural workers of appropriate safety measures. The Executive Board approved the draft project sheet subject to some further text revisions to be made by the project leads. The U.S. also committed to sharing information on

domestic occupational incidents (including adverse effects reporting) with NAFTA partners to explore reporting on a North American basis.

Pesticide Container Disposal

Mexico outlined the importance of developing regulations for the disposal of pesticide containers and identifying disposal and recycling alternatives. The U.S. expects to issue new standards for pesticide containers and bulk containment structures this summer, and is currently considering proposed new regulations for pesticide container recycling. Mexico will take the lead in organizing a conference call among federal, state, and provincial representatives to explore NAFTA TWG efforts directed at exchanging information related to disposal options, recycling, co-processing, and respective regulatory frameworks. The Executive Board noted that this was a good opportunity to share information among the NAFTA partners, and requested a status report from the leads at the next TWG meeting on this issue.

Multilateral and International Policy Updates

The country leads provided the Executive Board with updates on OECD and Codex activities of particular interest to the Executive Board and relevant to NAFTA activities. In all, the Executive Board reiterated its support for the multilateral efforts on pesticide regulation and noted the importance of global reviews and the substantive and important improvements in the Codex process for establishing MRLs.

The Executive Board also discussed the recent implementation of Japan's new MRL policy. Recognizing the value in supporting the Japanese government in this area, the NAFTA partners agreed to share information and work collaboratively as possible in this area.

NAFTA TWG Five-Year Strategic Plan

The Secretariat reviewed the current TWG 5-year Strategic Plan and proposed a process for the development of a new strategy for the next five years (2008-2013). The Executive Board provided feedback and directed work on proposed steps including developing goals and objectives, identifying priority initiatives, and seeking stakeholder input. Mexico will convene internal discussions to coordinate their participation in the development of the next 5-year plan.

The TWG Subcommittee co-chairs presented proposed performance indicators developed by taking into account stakeholder recommendations provided by each breakout group during the December 2005 meeting. The Executive Board noted that while performance indicators must be simple and understandable, they should encompass the broad range of activities undertaken by the NAFTA TWG and should be outcome and output oriented. The Executive Board asked the Secretariat to work with Subcommittee co-chairs to develop broad performance indicators for the TWG as a whole.

Adverse Effects Reporting

Following a presentation from Canada on opportunities for cooperation, the NAFTA countries agreed to develop a protocol for the exchange of information on adverse effects and incidence reporting.

New Projects

The Executive Board reviewed and approved two new project sheets for public release via posting on country websites:

- Data Harmonization Project Sheet NAFTA TWG efforts to harmonize data requirements for antimicrobial pesticides (U.S. requirements being developed under U.S. rule 40 CFR Part 158 W).
- Degradation Kinetics Project Sheet NAFTA TWG efforts to develop harmonized procedures for characterizing and quantifying pesticide persistence in environmental media as part of product evaluation.

Concluding Remarks

In their concluding remarks, the Executive Board members reiterated the value of continued collaborative actions on the various issues of importance discussed at the TWG meeting. The Executive Board commended the TWG for its noteworthy accomplishments to date and thanked Mexico for hosting the meeting and contributing to the success of the NAFTA TWG. Finally, the Executive Board approved a summary of key decisions reached, as well as resulting follow-up action items and time frames.

Next Meeting

The next Executive Board meeting will take place on December 6-8, 2006 in Montréal, Quebec, Canada. The Stakeholder session will be held on December 7, 2006.

APPENDIX A

Development of Science Based Flexibility with Regards to Residue Trial Requirements from the Subzones 5A, 5B and 1A

GOAL:

To develop an approach with regards to accommodating the need for residue trials from Zones 5A, 5B and 1A.

BACKGROUND:

In order to set Maximum Residue Limits (MRLs) appropriately, a specific number of field trials are conducted to measure pesticide residues in the edible portion of a crop. Field trials are conducted in a range of geographical areas or "zones" representative of the crop growing regions. The North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides developed a zone map for North America, which identifies distinct Subzones in Zones 1, 5 and 7. The existence of these Subzones (1A, 5A, 5B, 7A) often results in the need for separate residue trials to be conducted and poses a significant issue in the Minor Use Program in Canada as many minor crops are grown in the Subzones.

Previously, MRLs were set based on the highest residue from a field trial data set. Thus the importance of trials conducted in the representative growing regions for a crop, including the Subzones of 1A, 5A, 5B and 7A. However, the Pest Management Regulatory Agency (PMRA), in collaboration with the United States Environmental Protection Agency has recently developed a statistically-based method for establishing MRLs. This MRL statistical method accounts for the variability in the field trial data set. The PMRA has determined that, through the use of the MRL statistical method, flexibility can be offered to allow substitution of trials from Zone 1 for Subzone 1A and from Zone 5 for Subzones 5A and 5B. This substitution of trials is not expected to increase the risk of wrongly seizing a legally treated crop from the zones in question or increase the risk to the consumer.

At the National Crop Protection Meeting held in Ottawa, March 1, 2006, the PMRA announced, based on this flexibility that Zone 5= Subzone 5A= Subzone 5B and Zone 1= Subzone 1A. Registrants and Sponsors now have the option of conducting the trials required in Subzones 5A, 5B and 1A in Zone 5 and Zone 1, respectively, provided the total number of trials remain the same. Zone 7 does not equal Subzone 7A due to the irrigation practices in Subzone 7A.

OUTCOME:

As of March 1, 2006, the PMRA has made available to Registrants an option to substitute residue field trial data from Zone 1 or 5 for required trials from Subzone 1A or Subzone 5B, respectively as described above.